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09/955,672	09/19/2001	Kevin M. Moore	ADM-0003-00	1250

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EXAMINER

OH, TAYLOR V

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 03/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/955,672

Applicant(s)

MOORE ET AL.

Examiner

Taylor Victor Oh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 and 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Specification

The disclosure is objected to because of the following informalities:

on pages 4 , 7, lines 16 and 13, "98DC to about 100DC" and "160DC"
are written; on pages 9, 10 lines 5,10,11,22, a symbol "~" is used in front
of 2h or 100⁰ C or 5h or 7h.

They are improper. Appropriate correction is required.

Claim Objections

Claims 4, 5 ,16, and 17 are objected to because of the following informalities: a
term " zeolyte" is used.. Appropriate spelling correction is required.

Claim Rejections - 35 USC § 112

Claims 1,2, 4, 6, 13, 14, 16, 18, and 33 are rejected under 35 U.S.C. 112, first
paragraph, because the specification, while being enabling for an anhydrosugar alcohol,
such as, arabinitol, ribittol, D-mannitol, galactitol, iditol, 1,5:3,6-dianhydrohexitols,
1,4:3,6-dianhydrohexitols ,D-glucitol, and etc. does not reasonably provide enablement
for all the anhydrosugar alcohols known in the field of organic chemistry. The
specification does not enable any person skilled in the art to which it pertains, or with
which it is most nearly connected, to include all the anhydrosugar alcohols unrelated to
the invention commensurate in scope with these claims. Therefore, an appropriate
correction is required.

The specification, while being enabling for an acid catalyst, such as sulfuric acid, phosphoric acid, p-toluenesulfonic acid, p-methanesulfonic acid, and etc. does not reasonably provide enablement for all the acid catalysts in the field of organic chemistry. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all the acid catalysts unrelated to the invention commensurate in scope with these claims. Furthermore, an acid catalyst composition represent an unpredictable aspect in the art of organic chemistry. See *Exparte Sizco*, 9 USPQ 2d 2081 (Bd. Of App. And inter. March 1988). Therefore, an appropriate correction is required.

The specification, while being enabling for a soluble acid, such as sulfuric acid, phosphoric acid, p-toluenesulfonic acid, p-methanesulfonic acid, and etc. does not reasonably provide enablement for all the soluble acids in the field of organic chemistry. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all the soluble acids unrelated to the invention commensurate in scope with these claims. Therefore, an appropriate correction is required. Furthermore, there are “foreman factors or Wands factors” regarding unpredictability because a soluble acid includes any heterocyclic acid, any aromatic acid, any alicyclic acid, and a diverse scope of acyclic acids. In addition, it does not exclude any bi-functional acid such as a variety of amino acids.

Art Unit: 1625

Moreover, more than routine experimentation is involved. See In re Armbruster 185 USPQ 204 (CCPA 1985) and Angstadt et al. , 190 USPQ 152 (CCPA 1990).

The specification, while being enabling for a zeolite powder, such as CBV 3024, CBV 5534G, T-2665, or T-4480, and etc. does not reasonably provide enablement for all the a zeolite powder in the field of chemistry. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all the zeolite powder unrelated to the invention commensurate in scope with these claims. Therefore, an appropriate correction is required.

The specification, while being enabling for an acidic ion exchange resin, such as AG50W-X12, Amberlyst 15 or 35, or Dowex 50Wx 4, and etc. does not reasonably provide enablement for all the soluble acids in the field of organic chemistry. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all the acidic ion exchange resins unrelated to the invention commensurate in scope with these claims. Furthermore, there are the “foreman factors or wands factors” regarding unpredictability because ion-exchange resins include cationic exchangers and anionic exchangers and furthermore, they contain various types of ion-exchange resins such as gel type, porous type, high porous type, liquid type, and solid type. Because of the diverse scopes of their unique compositions and variations of physical structures, their corresponding catalytic activities are unpredictable. Therefore, more than routine experimentation is required and involved (second foremen factor).

Therefore, an appropriate correction is required.

Claims 1,13, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A phrase " organic solvents" is written. However, this does not specify what types of solvents are not employed in the process. Therefore, an appropriate correction is required.

A phrase " maintaining --- temperature" is written. However, this does not specify what temperature the dehydrating process is conducted. Therefore, an appropriate correction is required.

A phrase " a slurry-like isosorbide solution" is written. However, this does not explain what is the meaning of " a slurry-like isosorbide solution." Therefore, an appropriate correction is required.

A phrase " 35D C" is written. This is vague and there is no meaning of the symbol. Therefore, an appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1625

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Hartmann (U.S. 3,454,603).

Hartmann discloses a process of preparing 1,4-3,6-dianhydroglucitol by heating hexitols, such as 1,4 D,L-allitan or 1,4 D,L-dulcitan, in the presence of an acid dehydration catalyst, such as sulfuric acid, p-toluenesulfonic acid (see col. 2, lines 25-40), and then distilling the reaction mixture to recover dianhydrohexitols at extremely low pressures (below 1.0 mmHg) (see col. 2, lines 59-61). In addition, the products may be further purified by redistillation (see col. 2, line 69). This is identical with the claims.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1625

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartmann (U.S. 3,454,603) in view of Feldmann et al (U.S. 4,564,692) and Brinegar et al (WO 00/14081).

Hartmann discloses a process of preparing 1,4-3,6-dianhydroglucitol by heating hexitols, such as 1,4 D,L-allitan or 1,4 D,L-dulcitan, in the presence of an acid dehydration catalyst, such as sulfuric acid, p-toluenesulfonic acid (see col. 2, lines 25-40) at a temperature of from 110 to 185⁰ C. (see col. 2, lines 49-51), and then distilling the reaction mixture to recover dianhydrohexitols at low pressures of from 0.03 to 100 mmHg (see col. 2, lines 56-61). In addition, the products may be further purified by recrystallization (see col. 2, lines 69-71).

The instant invention differs from Hartmann in that melt crystallizing, filtering, and centrifuging the anhydrosugar alcohol are unspecified; the acidic ion exchange resin is added in an amount of from 0.01 to 0.15 gram equivalents to sugar alcohol; the

Art Unit: 1625

acid catalyst contains a zeolite powder selected from CBV 3024, CBV 5534G, AG50W-X12; the period is from 30 to 45 minutes during the cooling .

Feldmann et al teaches a process of purifying the anhydro sugar alcohols by crystallization from a concentrated solution (see col. 1 ,lines 6-10) in the absence of organic crystallization solvents (see col. 1 ,lines 65-67). Furthermore, all aqueous anhydro sugar alcohol solutions with a suitable concentration have been obtained from acid-catalyzed dehydration of hexitols (see col. 4 ,lines 9-11) with strongly acidic cationic exchange resins (see col. 4 ,lines 60-61); the crystalline anhydro sugar alcohols can be separated from the mixture by centrifugation or filtration (see col. 4 ,lines 25-27). In addition, if the heavy liquors contain two or more different anhydro sugar alcohols, it is possible to use fractional crystallization in succession in order to produce the pure crystalline form (see col. 4 ,lines 35-39); also, it is advisable to conduct the crystallization process at a temperature of from 20 to 65⁰ C. (see col. 3 ,lines 18-19).

Concerning the addition of the amount of from 0.01 to 0.15 gram equivalents of resin to sugar alcohol and the cooling period from 30 to 45 minutes, the limitation of a process with respect to ranges of pH, ratio and period does not impart patentability to a process when such values are those which would be determined by one of ordinary skill in the art in achieving optimum operation of the process. Ratio and period are well understood by those of ordinary skill in the art to be result-effective variables, especially

Art Unit: 1625

when attempting to control selectivity of a chemical process in the absence of an unexpected result.

With respect to the use of the acid catalyst containing the zeolite power selected from CBV 3024, CBV 5534G, AG50W-X12, the prior art references are silent. However, it is well-known in the art that AG50W-X12 acidic catalyst can be used with an advantage of little or no residue in producing anhydro sugar alcohols as shown in Brinegar et al (see page 7, lines 5-6). Therefore, it would have been obvious to the skilled artisan in the art to have motivated to use the Brinegar et al AG50W-X12 as a substitute. This is because the skilled artisan in the art would expect to improve on the purity of the desired compound by using the AG50W-X12 catalyst in the process.

Hartmann does disclose the process of preparing 1,4-3,6-dianhydroglucitol by heating hexitols in the presence of sulfuric acid at a temperature of from 110 to 185° C., and then distilling the reaction mixture to recover dianhydrohexitols at low pressures, furthermore, the products may be purified by recrystallization. Also, Feldmann et al expressly teaches the process of purifying the anhydro sugar alcohols obtained from acid-catalyzed dehydration of hexitols by crystallization from a concentrated solution in the absence of organic crystallization solvents; moreover, when sugar alcohols are dehydrated, the reaction mixtures contain various impurities detrimental to the production of polyesters (see col. 1, lines 23-30). Therefore, it would have been obvious to the skilled artisan in the art to have motivated to incorporate the Feldmann et al crystallization technique into Hartmann in order to further purify the desired product

Art Unit: 1625

suitable for producing polyesters. This is because the skilled artisan in the art would expect to improve on the purity of the desired compound by applying the Feldmann et al crystallization technique to the Hartmann process.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Salzburg et al (U.S. 4,408,061) teaches a process for preparing 1,4-3,6-dianhydro-hexitols by eliminating water in the presence of hydrogen halide without using water and organic solvents at temperatures of up to 300⁰ C. and pressures of up to 250 Bar.

Hartmann (U.S. 3,160,641) teaches a process for purifying 1,4-3,6-dianhydro-hexitols by vacuum distillation of the acid catalyzed dehydration product of sorbitol. When sorbitol is dehydrated by heating with sulfuric acid under reduced pressure, isosorbide is isolated. Isosorbide may be recovered from the dehydration mixture by fractional distillation.

Salzburg et al (U.S. 4,506,086) teaches a process for preparing 1,4-3,6-dianhydro-hexitols from diacylation products of hexitols and organic compounds, such as carboxylic acids by subjecting them to a temperature of at least 130⁰ C.

Lueders et al (U.S. 4,861,513)) teaches a process for preparing polyalcohol mixture based on sorbitol by heating a reaction mixture containing D-sorbitol in the presence of an acid catalyst at a temperature of from 120 to 160⁰ C.

Art Unit: 1625

Stockburger (U.S. 4,297,290)) teaches a process for preparing sorbitan esters by forming anhydro sorbitol by acid-catalyzed anhydrization, then reacting the resultant anhydro sorbitol with a fatty acid in the presence of a base at a temperature of 215° C.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 703-305-0809. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-2742 for regular communications and 703-305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



February 27, 2003



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